REMARKS

Claims 22-57 presently appear in this case. No claims have been allowed. The official action of November 23, 2004, has now been carefully studied. Reconsideration and allowance are hereby respectfully urged.

Briefly, the present invention relates to a method for the treatment of viral infections by the administration of interferon via oromucosal contact. The dose is a high dose which is greater than 20 x 10^6 IU of interferon for a 70 kg human, preferably greater than 30 x 10^6 IU of interferon, which dose is in excess of a dose of the same interferon which induces a pathological response when parenterally administered.

Claims 36 and 38-57 have been rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. The examiner states that no support is seen in the specification for the word "orally" in the proviso in claim 36. Further, the examiner states that in claim 52, no support is found for the proviso "other than a rhinoviral infection." The examiner states that for subject matter to be excluded by proviso, the specification must disclose that said matter can be excluded. In the instant specification, there is no indication that the treatment of

other viruses is preferred over the treatment of rhinovirus.

This rejection is respectfully traversed.

With respect to support in the specification for the term "orally", this term does not appear *in haec verba*. However, the concept of oromucosal administration through the mouth appears in the specification. As stated on page 12, lines 11 and 12 of the specification:

> The IFN may be administered by any means which provides contact of the IFN with the oromucosal cavity of the recipient.

It goes on to state that:

> This may be achieved with liquids, solids, or aerosols, as well as nasal drops or sprays.

The next sentence reads:

> Thus, the invention includes, but is not limited to, liquid, spray, syrup, lozenges, buccal tablets, and nebuliser formulations.

Those of ordinary skill in the art reading the present specification would be well aware that there are two ways of administering a medication oromucosally, either by means of nasal drops or sprays that are selected so as to coat the oromucosal cavity (as opposed to small droplets that are sprayed directly into the lung), or through the mouth, which is the only way to administer a lozenge, a buccal tablet, a syrup, etc., to the oromucosal cavity. Accordingly, the concept of applying through the mouth is present in the specification, and specifying this in the claims is not new

matter. Note, for example, *In re Anderson,* 176 USPQ 331, 336 (CCPA 1973), where the court reversed a new matter rejection (which would now be termed a written description rejection) based on Appellant's change of the claim terminology "containing a medicament" to "carrying a medicament." The court reasoned:

> The question, as we view it, is not whether "carrying" was a word *used* in the specification as filed, but whether there is *support* in specification for employment of the term in a claim; is the concept of carrying present in the original disclosure? We think it is.

Here, the concept of oromucosal administration by administration through the mouth is a concept that is present in the original disclosure. Note further the guidelines for the examination of patent applications under the written description requirement appearing in MPEP 2163. See particularly Section I.B, where it states:

> While there is no *in haec verba* requirement, newly added claim limitations must be supported in the specification through express, implicit, or inherent disclosure.

See also Section II.A.3.(b), where it states:

> To comply with the written description requirement of 35 U.S.C. §112, para. 1, ... each claim limitation must be expressly, implicitly, or inherently supported in the originally filed disclosure.

Clearly, in this case the concept of oromucosal administration through the mouth is implicit in the above-quoted sections of the specification. Applicant clearly was in possession of

both oromucosal administration through the mouth and through the nose. Use of this term in the claim is not new matter.

In order to eliminate any confusion as to whether the term "oral" means administration through the digestive system by swallowing, the term "orally" has now been changed to read "through the mouth" in the claims. There is sufficient written description by inherent and implicit disclosure as discussed above to comply with the first paragraph of 35 U.S.C. §112. Reconsideration and withdrawal of this part of the rejection is therefore respectfully urged.

With respect to 'rhinoviral infection," note that this was listed as a species of the invention at page 10, line 25. As the specification discloses the genus and rhinovirus as one of the species, it necessarily discloses the whole minus the specifically mentioned species.

With respect to the examiner's statement that, for subject matter to be excluded by proviso, the specification must disclose that said matter can be excluded, it is urged that this is not the current state of the law. As stated in MPEP 2173.05(i):

> Any negative limitation or exclusionary proviso must have basis in the original disclosure. If alternative elements are positively recited in the specification, they may be explicitly excluded in the claims. See *In re Johnson*, 558 F.2d 1008, 1019, 194 USPQ 187, 196 (CCPA 1977) ("[the] specification, having described the whole, necessarily described the part remaining.").

The *Johnson* case cited in the MPEP states at 196:

> The notion that one who fully discloses and teaches those skilled in the art how to make and use, a genus and numerous species therewithin, has somehow failed to disclose, and teach those skilled in the art how to make and use, that genus minus two of those species, and has thus failed to satisfy the requirement of §112, first paragraph, appears to result from a hypertechnical application of legalistic prose relating to that provision of the statute. All that happened here is that Appellants narrowed their claims to avoid having them read on a lost interference count.

Similarly, here, all that applicant has done is narrow the claim to avoid it reading over a reference that is very specific to rhinovirus. There is no requirement in any of the case law that there be an indication that the treatment of other viruses is preferred over the treatment of rhinovirus. Having described the whole, one has necessarily described the whole minus one of the specifically described species. Therefore, there is written description requirement. Reconsideration and withdrawal of this part of the rejection are also respectfully urged.

Claim 37 has been rejected under 35 U.S.C. §103(a) as being unpatentable over Eby. The examiner states that applicant's argument that claim 37 requires greater than about 30×10^6 IU of interferon is not persuasive because the recitation "greater than about" would include the amount

disclosed in Eby, since "about" could be considerably less than the amount recited.

Claim 37 has now been amended to delete the term "about". Claim 37 now requires greater than 30 x 10^6 IU of interferon. This does not read on what is disclosed in Eby and, accordingly, this rejection has now been obviated. Reconsideration and withdrawal thereof are therefore respectfully urged.

Claims 22-57 have been rejected under 35 U.S.C. §103 as being unpatentable over Amgen, and claims 22-57 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Amgen in view of Feinberg. The examiner states that applicant's argument that orally and nasally administered IFN-con disclosed in Amgen must enter the bloodstream to produce the effects observed for parenteral administration is not persuasive. The examiner states that applicant recites a property that results from oromucosal administration, not a new method of use. The examiner states that it would be inherent that this would also occur in the method of Amgen, and that even if this were not inherent, data presented in the specification demonstrates that only IFN-α is not absorbed into the bloodstream, and only claims 27 and 43 recite IFN-α. This rejection is respectfully traversed.

The only disclosure about mode of administration in Amgen is at page 13, line 23-37, where it states:

> The route of administration will preferably be by injection into the blood of a mammal where the injection may be intravenous, intramuscular, subcutaneous or intralesional. Administration may also be by oral or nasal routes.

Interpreting this, one must understand what is the invention disclosed in Amgen. The invention has nothing whatsoever to do with new methods of administration of interferon. As stated in the paragraph bridging pages 8 and 9:

> The subject invention provides for a method of treating a condition treatable by alpha interferon by reducing or eliminating one or more side effects typically associated with alpha interferon treatment, involving administering a therapeutically effective amount of IFN-con to a patient.

Thus, the invention is directed to any method known for treatment by alpha interferon, with the improvement being that the alpha interferon is more specifically IFN-con.

Prior to the present invention, it was thought that in order to treat viral infections with interferon, the interferon must enter the bloodstream. This is why Amgen explicitly states that the preferred mode of administration is injection into the bloodstream. Indeed, Amgen's disclosure of the antiviral assay to use in the sentence bridging pages 1 and 2 refers to the assay in US patent no. 4,241,174. This assay involves direct contact of the interferon with a cell line known to be sensitive to the interferon, and then adding challenge virus. Clearly, Amgen persists in the conventional

wisdom that in order for interferon to be effective, it must come in direct contact with the virus or with the cells being protected.

The present invention is based on the discovery that the activity of interferon does not involve direct action of interferon. See the paragraph in the present specification at page 34 beginning at line 12, where it states:

> Without wishing to be bound by any proposed mechanism for the observed beneficial effect, our results suggest that oromucosally administered IFN exerts its effects against tumor cells or against viruses via a presently undefined novel mechanism, which does not involve a direct action of exogenously administered IFN, or the induction of endogenous IFN. This is supported by the absence of detectable levels of circulatory IFN or of the three biomarkers tested. It appears that this mechanism may act at least partly by stimulation of the abundant lymphoid tissues surrounding the nasopharyngeal and oral cavities.

The examiner appears to believe that, when administering in the manner disclosed by Amgen, one will inherently get the properties that result from oromucosal administration. However, this is not correct, as Amgen contains no explicit statement that oromucosal administration is contemplated. Oral administration usually means by swallowing, i.e., through the gut, not by oromucosal administration. Similarly, nasal administration usually means administration directly into the lungs to make direct contact

with virus there. It does not usually mean administering in such a way as to remain in the nasopharyngeal cavity. Thus, this is not an anticipation rejection where inherency is relevant.

Given the fact that there is no explicit disclosure of oromucosal administration, and those of ordinary skill in the art would understand from reading Amgen that direct contact with the virus or the cells to be protected is necessary, there would be no motivation by anyone reading either Amgen or Feinberg to administer in such a way that does not involve direct action of the interferon on virally infected cells and wherein the interferon does not enter the bloodstream. Accordingly, reconsideration and withdrawal of this rejection is also respectfully urged.

It is submitted that all of the claims now present in the case clearly define over the references of record and fully comply with 35 U.S.C. §112. Reconsideration and allowance are therefore earnestly solicited.

Respectfully submitted,

BROWDY AND NEIMARK, P.L.L.C.
Attorneys for Applicant(s)

By _____
Roger L. Browdy
Registration No. 25618

RLB:jab
Telephone No.: (202) 628-5197
Facsimile No.: (202) 737-3528
G:\BN\P\phaq\Tovey1A\Pto\AmendmentJ.doc